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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,538	07/10/2003	Preeti Lal	PF-0471-3 DIV	8127

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,538	LAL ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 1003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 1-2 and 17-18, drawn to an isolated polypeptide and compositions thereof; classified in Class 530, subclass 350.

2. Claims 3-7 and 12-13, drawn to an isolated polynucleotide, and cells comprising said polynucleotide; classified in Class 536, subclass 23.1.

3. Claim 8, drawn to a transgenic organism; classified in Class 800, subclass 8.

4. Claims 9-10, drawn to a method of producing a polypeptide; classified in Class 435, subclass 69.1.

5. Claims 11, 31-32, 34, 36-38, and 40-43, drawn to isolated antibodies, classified in Class 530, subclass 387.1.

6. Claims 14-16, drawn to a method of detecting a target polynucleotide by hybridization with a probe; classified in Class 536, subclass 24.31.

7. Claim 16, drawn to a method of detecting a target polynucleotide by amplification using polymerase chain reaction; classified in Class 536, subclass 24.33.

8. Claim 19, drawn to a method for treating a disease comprising administering a polypeptide; classified in Class 514, subclass 2.

9. Claim 20, drawn to a method of screening a compound for effectiveness as an agonist of a polypeptide; classified in Class 530, subclass 350.

10. Claim 21, drawn to a composition comprising an agonist compound of a polypeptide; classified in Class 530, subclass 300.

11. Claim 22, drawn to a method for treating a disease comprising administering an agonist of a polypeptide; classified in Class 424, subclass 184.1.

12. Claim 23, drawn to a method of screening a compound for effectiveness as an antagonist of a polypeptide; classified in Class, 530 subclass 350.

13. Claim 24, drawn to a composition comprising an antagonist compound of a polypeptide; classified in Class 530, subclass 323.

14. Claim 25, drawn to a method for treating a disease comprising administering an antagonist of a polypeptide; classified in Class 424, subclass 278.1.

15. Claim 26, drawn to a method of screening for a compound that binds to a polypeptide; classified in Class 435, subclass 7.1.

16. Claim 27, drawn to a method of screening for a compound that modulates the activity of a polypeptide by comparing the activity of a polypeptide in the presence and absence of a compound; classified in Class 530, subclass 350.

17. Claim 28, drawn to a method of screening a compound for effectiveness in altering expression of a polynucleotide; classified in Class 435, subclass 6.

18. Claim 29, drawn to a method of screening for potential toxicity of a test compound; classified in Class 536, subclass 24.3.

19. Claim 30, drawn to a method for a diagnostic test for a disease comprising detecting expression of EVL1 in a biological sample; classified in Class 530, subclass 388.1.

20. Claims 33 and 35, drawn to a method of diagnosing a disease comprising administering an antibody to a subject; classified in Class 424, subclass 178.1.

21. Claims 36 and 39, drawn to a method of preparing a polyclonal or monoclonal antibody; classified in Class 530, subclass 387.1.

22. Claim 44, drawn to a method of detecting a polypeptide with an antibody; classified in Class 530, subclass 387.9.

23. Claim 45, drawn to a method of purifying a polypeptide with an antibody; classified in Class 530, subclass 388.1.

24. Claims 46 and 48-55, drawn to a microarray; classified in Class 536, subclass 24.3.

25. Claim 47, drawn to a method of generating an expression profile of a sample using a microarray; classified in Class 536, subclass 24.31.

2. Groups 1-3, 5, 10, 13, and 24, are different products. Nucleic acids, polypeptides, antibodies to the polypeptides, transgenic organisms, agonist compounds, antagonist compounds, and microarrays differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups 4, 6-9, 11-12, 14-23, and 25 are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods comprising different method steps, different reagents, resulting in different endpoints.

4. Groups 1 and 6-7, 11, 14, 17-23, 25 are unrelated because the product of group 1 is not used or otherwise involved in the process of groups 6-7, 11, 14, 17-23, 25.

5. Groups 2 and 8-9, 11-12, 14-16, 19-23, 25are unrelated because the product of group 2 is not used or otherwise involved in the process of groups 2 and 8-9, 11-12, 14-16, 19-23, 25.

6. Groups 3 and 6-9, 11-12, 14-23, 25 are unrelated because the product of group 2 is not used or otherwise involved in the process of groups 6-9, 11-12, 14-23, 25.

7. Groups 5 and 6-9, 11-12, 14-18, 25 are unrelated because the product of group 5 is not used or otherwise involved in the process of groups 6-9, 11-12, 14-18, 25.

8. Groups 10 and 6-9, 12, 14-23, 25 are unrelated because the product of group 10 is not used or otherwise involved in the process of groups 6-9, 12, 14-23, 25.

9. Groups 13 and 6-9, 11-12, 15-23, 25 are unrelated because the product of group 13 is not used or otherwise involved in the process of groups 6-9, 11-12, 15-23, 25.

10. Groups 1 and 8-9, 12, 15-16 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptide could be used as a molecular weight marker in a western blot.

11. Groups 2 and 6-7, 17-18 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polynucleotide could be used as a molecular weight marker in a northern blot.

12. Groups 5 and 19-20 and 22-23 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody could be used to generate anti-idiotypic antibodies.

13. Groups 6 and 21 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polyclonal antibodies could be made in vitro by culturing B cells with the polypeptide, and the monoclonal antibodies could be made by screening a phage library.

14. Groups 10 and 11 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the agonist compound could be used to generate agonist specific antibodies.

15. Groups 13 and 14 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antagonist compound could be used to generate antagonist specific antibodies.

16. Groups 1 and 4 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide could be made using a protein synthesizer.

17. Groups 24 and 25 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the expression profile could be determined by performing PCR with a set of primers derived from SEQ ID NO: 2.

18. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by their recognized divergent subject matter. Further, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

19. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

21. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light *of In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Amy E. Juedes whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 10, 2006

5/22/06
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